Beyond Clinical: Integrating Research Assay Data into the Observational Health Data Sciences and Informatics Common Data Model (OHDSI CDM) through the Surgical Critical Care Initiative (SC2i)

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Background

The Uniformed Services University (USU) Surgical Critical Care Initiative (SC2i) is a Department of Defense funded consortium of seven Federal and non-Federal institutions which aims to improve the care of critically wounded service members and civilians by facilitating the development, translation, and dissemination of data-driven care models relevant to patients. This mission is enabled through biomarker discovery on a vast trauma dataset that harmonizes 30+ million high-quality clinical, laboratory, and bio-bank data elements.

In the process of mapping this dataset to the Observational Health Data Sciences and Informatics Common Data Model (OHDSI CDM), it was discovered that OHDSI CDM primarily captures clinical data. Moreover, the ability to incorporate various forms of assay data from disparate sources is critical for SC2i exploratory and translational clinical research. Our aim was to incorporate the SC2i's extensive research assay data model into the OHDSI CDM, in order to translate research assay development to precision medicine.

Methods

In its mission to bring highly personalized diagnoses and therapeutic interventions to its wounded service members, the SC2i incorporates best practices in informatics to ensure high-quality biomarkers are available for research activities. All laboratory-based measurements are generated under Good Clinical Laboratory Practices (GCLP). All capture of clinical information includes a tiered review to ensure accuracy and continually improve the process to reduce errors.

The original centralized SC2i data model was implemented in a proprietary and flexible fashion and was adapted continually over a five year span to support research and discovery. Over the past year, a project has commenced to map the proprietary model to OHDSI CDM. Variables are simultaneously being mapped to corresponding standard concepts and identified using Usagi and Athena. The transformation is being developed in Python and stored in a PostgreSQL database, viewable for user acceptance testing through the pgAdmin interface.

Results

The Tissue and Data Acquisition Protocol (TDAP) dataset (primary dataset of Surgical Critical Care Initiative) is comprised of clinical, assay, and bio-bank data for more than 1,000 patients across a combined military and civilian cohort. Within this data set, we searched for Standard Concept IDs for mapped variables using Athena. The TDAP dataset data dictionary includes 11,000 variables. Of these, it was found that 1,000 are from research assays, which did not have a mapping within the OHDSI OMOP CDM. The SC2i created a new dictionary for these research assays in the MEASUREMENT table.

Conclusion

The SC2i utilizes high-quality standardized data across multiple settings. Data which is critical to the development of clinically relevant Clinical Decision Support Tools (CDSTs). Such tools are key to improvements in the precision medicine for surgical critical care and are expected to improve outcomes and resource utilization in both civilian and military health systems. The addition of a SC2i assay concept code and relationship hierarchy and its submission to expand available vocabularies in Athena will enable the capture and distinction of a variety of different assay result types. By adding an extensive library of research assays, not only can SC2i use this data to create biology-driven CDSTs, but others will be able to implement new translational and precision medicine endeavors well beyond observational clinical data.

References/Citations